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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,369	08/29/2001	Ahmad Yekta	1191/IH584-US1	9064

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EXAMINER

NILAND, PATRICK DENNIS

ART UNIT	PAPER NUMBER
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1714

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

5

Office Action Summary**Application No.**

09/943,369

Applicant(s)

YEKTA ET AL.

Examiner

Patrick D. Niland

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/2/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. The amendment of 12/2/05 has been entered. Claims 17-31 are pending.
2. Claims 17-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A. There is not basis in the originally filed specification for the newly added recitation of “wherein the concentration of the dye is adjusted such that the fluorescent signal of the dye in the medium of the secondary standard after gelling the mixture is at least approximately equal to the fluorescent signal of a known concentration of the dye in a second medium of the analyte sample measurement, and wherein the medium of the secondary standard is different than the second medium of the analyte sample measurement”. Page 14, lines 9-11 is noted but the statement there is not equivalent in scope to the instant claim limitation and the newly added scope is new matter. The argued examples do not provide support for the full scope of the above cited claim portion, only for the subject matter encompassed by the examples which is much smaller in scope.

The instant claims do not require close mimicking of a primary standard. They require the newly presented language, which differs substantially from requiring “close mimicking of a primary standard” and there is not support in the originally filed specification for this newly presented language. The applicant’s arguments are not commensurate in scope with the newly presented claim language.

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3. Claims 17-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. It is unclear what is to constitute the claimed “adjusted”. “Adjusted” implies that some dye is present and then some more is added or some is taken out in response to some determination. It is unclear if one simple addition is acceptable or if “adjusted” requires the dye to be added in more than one step.

B. It would appear that a given amount of dye in a secondary standard would always give a fluorescent signal for which some “known concentration of dye in a second medium of the analyte sample measurement” would give an equivalent fluorescent signal. It is therefore unclear how the new limitation is to differentiate any method of mixing dye and the instantly claimed polymer from any other method of mixing dye and the instantly claimed polymer. Beer’s law and consideration of any analyte analyzable using fluorescence would make this so. Furthermore, as the instant claims are directed to making a standard, not analyzing anything and do not require anything to have been analyzed, it is unclear how one is required to know the concentration of any dye or to have considered all of the factors of any given analyte medium that affect the final fluorescent signal. It is also unclear what constitutes the second medium in this claim. It is unclear if it requires the analyte to be present or only some carrier phase without analyte. Furthermore, when one prepares a standard, it is inherent that one prepares a standard which will give a signal within the order of that which will be obtained from actual samples to be analyzed as the calibration curves would be inaccurate otherwise as would be understood from undergraduate chemistry courses which taught spectral analysis, i.e. well known. It is unclear

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how the newly presented limitation discussed above differentiates over the definition of “standard”.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 17-23, 27, and 30-31 are rejected under 35 U.S.C. 102(a) as being anticipated by US Pat. No. 6485703 Cote et al..

Cote discloses the instantly claimed method for preparing secondary standards and the compositions used therein at the abstract; column 6, lines 9-67; column 7, lines 45-47, which will necessarily give a viscosity change with pH change and/or with temperature change; column 8, lines 27-44; and the remainder of the document, e.g. Cote mixes dye with viscosity changing polymer. The polymers will be amorphous and are therefore liquid by definition. Phase changing hydrogel is disclosed at column 9, lines 55-65. The mixture will necessarily be placed into an instrument’s container, which falls within the scope of the instant claims 17-23 and 27. The applicant’s argument re “consisting essentially of” is not persuasive because the component that the applicant states that they wish to exclude of Cote is the component which falls within the scope of the instantly claimed viscosity changing polymers. The instant claims do not exclude

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the properties argued by the applicant. "Consisting essentially of" does not exclude any other component of the patentee because no other component has been shown to materially affect the basic and novel characteristics of the instant claims. The applicant has not shown the additional ingredients of the reference to materially affect the basic and novel characteristics of the composition. It is therefore not seen that "consisting essentially of" excludes anything from the composition of the reference. See *In re Janakirama-Rao*, 317 F 2d 951, 137 USPQ 893 (CCPA 1963) and *Ex parte Davis et al.*, 80 USPQ 448 (PTO Bd. App. 1948). The "gelling" step of the claims necessarily occurs in the polymer of the patentee because it is a hydrogel. The argument that the patentee does not disclose or suggest a process for preparing a standard, or a process for preparing a container for calibrating an instrument, comprising gelling a mixture and therefore, Cote does not anticipate claims 17-23 and 27 is not persuasive because the patentee performs the instantly claimed method steps. It is not seen that the recitation "for preparing a secondary standard" further defines the process by requiring anything other than the steps recited after "of:" nor that the method of the reference does not result in a product which could be used as a secondary standard after finishing the method steps which are the subject of the instant claims. The applicant provides no evidence that an analyte sensitive material is not necessarily and inherently used as a standard because a standard need never contact said analyte by definition of "standard". The patentee's abstract states that, in the disclosed methods for analyte detection, they provide hydrogel particles which undergo a measurable change in properties as a function of their interaction with analytes. Thus, they are clearly detecting the hydrogel particles rather than the analyte. Thus, the hydrogel particles of the patentee are secondary standards as defined in the applicant's specification, page 5, lines 19-24 because they behave as a secondary standard is

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described on page 5 of the instant specification. It is not seen that “closely mimics” nor “secondary standard” does not encompass the interaction described by Cote to give the detectable event. The standard of Cote would appear to be secondary in that the detected component is not the analyte per se but the hydrogel albeit as it is effected by the analyte. This would seem to distinguish the standard of the reference from being “primary” and thus make it “secondary”. The Applicant’s argument that the product of Cote contains the analyte is not persuasive since the analyte of the instant claims may be anything analyzable. The instant claims do not exclude the standard from containing or not containing the analyte nor do they specify what the analyte is. In the instant claims which are directed to the method of making the standard, there is no analyte defined. This argument does not distinguish the instant claims over the reference therefore. The recited future intended use of the resulting product of the method of the patentee and the instant claims is not material in determining whether the process of the instant claims 17-23 and 27 is novel because it does not further limit the process of the instant claims so as to remove the process of the patentee as anticipating it because the product resulting from the process of the patentee necessarily and inherently can be used in these future processes and the product of the process of the patentee will be in some type of container.

The applicant’s amendment requiring “wherein the concentration of the dye is adjusted such that the fluorescent signal of the dye in the medium of the secondary standard after gelling the mixture is at least approximately equal to the fluorescent signal of a known concentration of the dye in a second medium of the analyte sample measurement and wherein the medium of the secondary standard is different than the second medium of the analyte sample measurement” is not persuasive because the event measured in Cote is dependant on the interaction of the

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hydrogel containing dye of Cote with the analyte. Thus, “the concentration of the dye” of Cote must necessarily give “the fluorescent signal of the dye in the secondary standard after gelling the mixture [which] is at least approximately equal to the fluorescent signal of a known concentration of the dye under conditions of the analyte sample measurement” because conditions of analyte sample measurement are required to detect the events of the hydrogel of Cote used for detection. Stated more simply, 6 units of the dye of Cote will give the same measurement as 6 units of the dye of Cote where both are in the analyte which gives the action described in Cote’s abstract. The choice of 6 units is arbitrary but adding any amount of the dye constitutes adjusting the concentration from 0 to that added amount and is in fact the “adjustment” of the instant claims. Adding the dye of Cote to the hydrogel of Cote, i.e. changing the concentration from 0 to any non-zero value, falls within the “adjusting” of the instant claims. The newly added limitation therefore encompasses any amount of dye that may be used by the patentee and therefore does not differentiate the instantly claimed inventions from those disclosed by the patentee. Inherent in the abstract’s statement that the hydrogel particles are useful to detect one or more selected analytes and the fact that the thing being detected is the dye in the hydrogel is that the amount of dye in the hydrogel, i.e. the medium of the secondary standard has to give a signal corresponding to something in the analyte medium whether the analyte medium is the same as the hydrogel or different. To quantify what is found, the signal in the hydrogel of Cote must necessarily be calibrated such that it corresponds with the signal of a known concentration of something in the analyte medium, either directly or via calculation. This correspondence of the signal of the dye in the polymer of Cote and the unknown in the analyte necessarily gives a

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correspondence to the signal generated by a calculable, i.e. known, amount of dye in the analyte matrix. This rejection is therefore maintained.

7. Claims 17-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6485703 Cote et al. in view of US Pat. No. 6077669 Little et al..

Cote discloses the instantly claimed methods as discussed in paragraph 6 above. Arguments relating to Cote and the newly added amendments are addressed in paragraph 6 above also.

It would have at least been obvious to one of ordinary skill in the art to calibrate an instrument using these mixtures because the ordinary skilled artisan would recognize that the reading measured from the signal described in the abstract of Cote must somehow be correlated to an amount of analyte. The process of making this correlation is "standardizing" the measurement. This process is well known for any measuring device as is the instant fluorescent analyzation. Note that Cote discloses measuring optical properties and the choice of the fluorescent optical properties is well known as seen from the references cited by the applicant at page 4 of the instant specification. This would be calibration or standardization and is discussed at column 8 of Little et al.. It would have been obvious to one of ordinary skill in the art to use ammonia gas to achieve whatever the desired pH should be because this is a well known manner to affect pH and would be readily applicable to the systems of Cote. The applicant's argument re "consisting essentially of" is not persuasive because the component that the applicant states that they wish to exclude of Cote is the component which falls within the scope of the instantly claimed viscosity changing polymers. The instant claims do not exclude the properties argued by the applicant. "Consisting essentially of" does not exclude any other component of the patentee because no other component has been shown to materially affect the basic and novel

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characteristics of the instant claims. The applicant has not shown the additional ingredients of the reference to materially affect the basic and novel characteristics of the composition. It is therefore not seen that "consisting essentially of" excludes anything from the composition of the reference. See *In re Janakirama-Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963) and *Ex parte Davis et al.*, 80 USPQ 448 (PTO Bd. App. 1948). The "gelling" step of the newly added claims necessarily occurs in the polymer of the patentee because it is a hydrogel. The argument that the patentee does not disclose or suggest a process for preparing a secondary standard, or a process for preparing a container for calibrating an instrument, comprising gelling a mixture and therefore, Cote does not anticipate claims 17-23 and 27 is not persuasive because the patentee performs the instantly claimed method steps. The recited future intended use of the resulting product of the method of the patentee and the instant claims is not material in determining whether the process of the instant claims 17-23 and 27 is novel because it does not further limit the process of the instant claims so as to remove the process of the patentee as anticipating it because the product resulting from the process of the patentee necessarily and inherently can be used in these future processes and the product of the process of the patentee will be in some type of container. The applicant's arguments regarding whether or not Little discloses viscosity changing polymers is not persuasive because all polymers have the ability to change viscosity with some changing environmental factor such as temperature, pH, etc.. This argument ignores the reason for which Little was clearly cited above and the fact that Cote is the primary reference cited for this factor with Little cited to explain, as stated above. The newly added limitation therefore encompasses any amount of dye that may be used by the patentee and therefore does not differentiate the instantly claimed inventions from those disclosed by the patentee. Inherent

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in the abstract's statement that the hydrogel particles are useful to detect one or more selected analytes and the fact that the thing being detected is the dye in the hydrogel is that the amount of dye in the hydrogel, i.e. the medium of the secondary standard has to give a signal corresponding to something in the analyte medium whether the analyte medium is the same as the hydrogel or different. To quantify what is found, the signal in the hydrogel of Cote must necessarily be calibrated such that it corresponds with the signal of a known concentration of something in the analyte medium, either directly or via calculation. This correspondence of the signal of the dye in the polymer of Cote and the unknown in the analyte necessarily gives a correspondence to the signal generated by a calculable, i.e. known, amount of dye in the analyte matrix. For the reasons stated in this paragraph and in paragraph 6 above, this rejection is therefore maintained.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

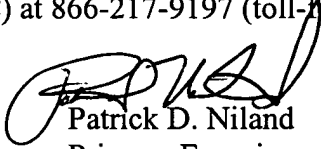
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick D. Niland whose telephone number is 571-272-1121. The examiner can normally be reached on Monday to Thursday from 10 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan, can be reached on 571-272-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Patrick D. Niland
Primary Examiner
Art Unit 1714